

CLAIM LISTING:

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently amended) An acid addition salt of a 5-aminolevulinic acid (5- ALA) ~~derivative ester~~ with an acid which has a pKa of about 5 or less, wherein said acid is a sulfonic acid, a sulfonic acid derivative, ~~sulfuric acid, or~~ nitric acid ~~or phosphoric acid.~~, wherein said 5-ALA ester is a compound of formula X:



wherein R^1 represents a straight-chained C_{1-6} alkyl group optionally substituted by an aryl group, and

R^2 each independently represents a hydrogen atom or an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more $-\text{O}-$, $-\text{NR}^3-$, $-\text{S}-$ or $-\text{PR}^3-$ groups; and

R^3 is a hydrogen atom or a C_{1-6} alkyl group.

2. (Cancelled)

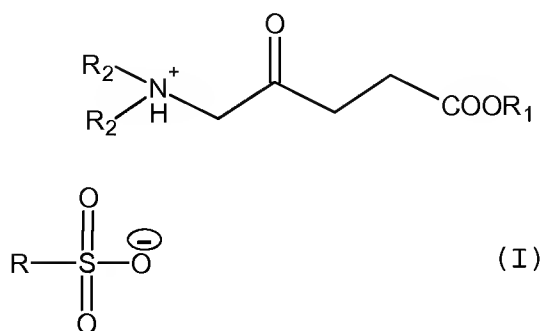
3. (Currently amended) An acid addition salt as claimed in claim [[2]] 1, wherein in formula X, ~~R^1 either represents an unsubstituted alkyl group or an alkyl group substituted by an aryl group and/or~~ each R^2 represents a hydrogen atom.

4. (Original) An acid addition salt as claimed in claim 2 or claim 3, wherein R^1 is a benzyl or substituted benzyl group.

5. (Currently amended) An acid addition salt as claimed in claim 2, wherein said compound of formula X is 5-ALA methyl ester, 5-ALA hexyl ester, 5-ALA benzyl ester, ~~5-ALA 2-methylpentyl ester, 5-ALA 4-methylpentyl ester,~~ 5-ALA 2-(2-ethoxyethoxy)ethyl ester, or 5-ALA 4-methylbenzyl ester ~~or 5-ALA 4-isopropylbenzyl ester.~~

6. (Original) An acid addition salt as claimed in claim 2, wherein said compound of formula X is 5-ALA methyl ester, 5-ALA hexyl ester or 5-ALA benzyl ester.

7. (Previously presented) An acid addition salt as claimed in claim 1, wherein said acid is an organic acid.
8. (Original) An acid addition salt as claimed in claim 7, wherein said acid is a sulfonic acid or a sulfonic acid derivative.
9. (Currently amended) An acid addition salt as claimed in claim 1 of formula I:



wherein R is a hydrogen atom or an optionally substituted alkyl or aryl group;

~~R¹ represents an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more -O-, -NR³-, -S- or -PR³- groups;~~

R² each independently represents a hydrogen atom or an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more -O-, -NR³-, -S- or -PR³- groups; and

R³ is a hydrogen atom or a C₁₋₆ alkyl group.

10. (Original) An acid addition salt as claimed in claim 9, wherein R is optionally substituted phenyl or methyl.
11. (Currently amended) An acid addition salt as claimed in claim 9 or claim 10, wherein in formula I, ~~R¹ either represents an unsubstituted alkyl group or an alkyl group substituted by an aryl group and/or~~ each R² represents a hydrogen atom.
12. (Previously presented) An acid addition salt as claimed in claim 9, wherein R¹ is a benzyl or substituted benzyl group.

13. (Currently amended) An acid addition salt as claimed in claim 9 which is a sulfonic acid addition salt of 5-ALA methyl ester, 5-ALA hexyl ester, 5-ALA benzyl ester, ~~5-ALA 2-methylpentyl ester, 5-ALA 4-methylpentyl ester, 5-ALA 2-(2-ethoxyethoxy)ethyl ester, or 5-ALA 4-methylbenzyl ester or 5-ALA 4-isopropylbenzyl ester.~~
14. (Original) An acid addition salt as claimed in claim 9 which is a sulfonic acid addition salt of 5-ALA methyl ester, 5-ALA hexyl ester or 5-ALA benzyl ester.
15. (Currently amended) An acid addition salt as claimed in claim 13 or claim 14, wherein said acid is ~~naphthalene~~ naphthalene-1,5-disulfonic acid, ethane-1,2-disulfonic acid, p-toluenesulfonic acid, methanesulfonic acid, dodecylsulfonic acid, naphthalene-2-sulfonic acid, benzenesulfonic acid, 2-hydroxy-ethanesulfonic acid, ethanesulfonic acid, or (+)-camphor-10-sulfonic acid.
16. (Cancelled)
17. (Currently amended) An acid addition salt as claimed in claim ~~[[16]]~~ 1, wherein said acid is ~~sulfuric acid, nitric acid or phosphoric acid, preferably nitric acid.~~
18. (Cancelled)
19. (Previously presented) An acid addition salt as claimed in claim 1, wherein said acid is pharmaceutically acceptable.
20. (Withdrawn) A process for preparing an acid addition salt as claimed in claim 1, said process comprising reacting a 5-aminolevulinic acid derivative with an acid as defined in claim 1.
21. (Withdrawn) A process for the preparation of an acid addition salt as claimed in claim 1, said process comprising the reaction of 5-aminolevulinic acid, or an esterifiable derivative thereof, with an alkanol or an ester-forming derivative thereof in the presence of an acid as defined in claim 1.
22. (Withdrawn) A process for the preparation of an acid addition salt as claimed in claim 1, said process comprising:
- (i) contacting a solution comprising a hydrochloride salt of an ALA derivative with a basic

- anion exchange resin;
- (ii) optionally removing said resin; and
- (iii) mixing the resulting solution with a solution comprising an acid as defined in claim 1.
23. (Withdrawn) A process for the preparation of an acid addition salt as claimed in claim 1, said process comprising:
- (i) reacting a hydrochloride salt of an ALA derivative with a silver salt of an acid as defined in claim 1, in a solvent in which AgCl is substantially insoluble; and
- (ii) optionally separating AgCl from the resulting salt.
24. (Previously presented) An acid addition salt obtainable by contacting a 5-ALA derivative with an acid as defined in claim 1.
25. (Currently amended) An acid addition salt obtainable by a process ~~as claimed in claim 20~~ comprising reacting a 5-aminolevulinic acid derivative with an acid as defined in claim 1.
26. (Previously presented) A pharmaceutical composition comprising an acid addition salt as claimed in claim 1, together with at least one pharmaceutical carrier or excipient.
27. (Previously presented) An acid addition salt or composition as claimed in claim 26 for use as a medicament.
28. (CANCELLED)
29. (Withdrawn) A method of photochemotherapeutic treatment of disorders or abnormalities of external or internal surfaces of the body, said method comprising administering to the affected surfaces, an acid addition salt or composition as claimed in claim 26, and exposing said surfaces to light.
30. (Previously presented) A product comprising an acid addition salt as claimed in claim 1, together with at least one surface-penetration assisting agent, and optionally one or more chelating agents as a combined preparation for simultaneous, separate or sequential use in treating disorders or abnormalities of external or internal surfaces of the body which are responsive to photochemotherapy.

31. (Previously presented) A kit for use in photochemotherapy of disorders or abnormalities of external or internal surfaces of the body comprising:
- a) a first container containing an acid addition salt as claimed in claim 1,
 - b) a second container containing at least one surface penetration assisting agent; and optionally
 - c) one or more chelating agents contained either within said first container or in a third container.
32. (Withdrawn) A method of in vitro diagnosis of abnormalities or disorders by assaying a sample of body fluid or tissue of a patient, said method comprising at least the following steps:
- i) admixing said body fluid or tissue with an acid addition salt as claimed in claim 1,
 - ii) exposing said mixture to light,
 - iii) ascertaining the level of fluorescence, and
 - iv) comparing the level of fluorescence to control levels.
33. (Withdrawn) A method of treating a condition that is responsive to photochemotherapy comprising administering to an area of the body affected by said condition an acid addition salt as claimed in claim 1.
34. (Cancelled)
35. (Previously presented) The acid addition salt as claimed in claim 1 wherein the acid has a pKa of about 3 or less.
36. (Previously presented) An acid addition salt as claimed in claim 3, wherein R¹ represents an unsubstituted C₁₋₆ alkyl or a C₁₋₂ alkyl substituted by an aryl group.
37. (Currently amended) An acid addition salt as claimed in claim ~~35~~ 36, wherein the C₁₋₂ alkyl substituent is phenyl.
38. (Cancelled)
39. (Previously presented) An acid addition salt as claimed in claim 11, wherein R¹ represents an unsubstituted C₁₋₆ alkyl or a C₁₋₂ alkyl substituted by an aryl group.

40. (Currently amended) An acid addition salt as claimed in claim ~~38~~ 39, wherein the C₁₋₂ alkyl substituent is phenyl.
41. (Withdrawn) A process as claimed in claim 20, wherein the 5-aminolevulinic acid derivative is an ALA ester.
42. (Withdrawn) A process as claimed in claim 21, wherein the ester-forming derivative is an alkanol.
43. (Withdrawn) A process as claimed in claim 22, wherein the acid addition salt is a compound of formula I.
44. (Withdrawn-Currently amended) A process as claimed in claim 22, wherein the hydrochloride salt of an ALA derivative is a compound of the formula Cl⁻ R₂²N⁺H-CH₂COCH₂CH₂CO₂R¹, wherein
- R¹ represents ~~a straight-chained C₁₋₆ alkyl group optionally substituted by an aryl group an optionally substituted straight chained, branched or cyclic alkyl group which may optionally be interrupted by one or more -O-, -NR³-, -S- or -PR³-groups;~~
- R² each independently represents a hydrogen atom or an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more -O-, -NR³-, -S- or -PR³- groups; and
- R³ is a hydrogen atom or a C₁₋₆ alkyl group.
45. (Withdrawn) A process as claimed in claim 22, wherein in step (iii) the acid is a sulfonic acid or a sulfonic acid derivative.
46. (Withdrawn) A process as claimed in claim 23, wherein the acid addition salt is a compound of formula I.
47. (Withdrawn-Currently amended) A process as claimed in claim 23, wherein the hydrochloride salt of an ALA derivative is a compound of the formula Cl⁻ R₂²N⁺H-

$\text{CH}_2\text{COCH}_2\text{CH}_2\text{CO}_2\text{R}^1$, wherein

R^1 represents a straight-chained C_{1-6} alkyl group optionally substituted by an aryl group ~~an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more -O-, NR^2 -, -S- or PR^3 -groups;~~

R^2 each independently represents a hydrogen atom or an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more -O-, NR^3 -, -S- or PR^3 - groups; and

R^3 is a hydrogen atom or a C_{1-6} alkyl group.

48. (Withdrawn) A process as claimed in claim 23, wherein in step (i) the acid is a sulfonic acid or a sulfonic acid derivative.

49. (Cancelled)

50. (Withdrawn) The method of claim 29 wherein the light is white light, light in the wavelength region 300-800 nm, or blue light in the wavelength region 380-440 nm.

51. (NEW) The acid addition salt of claim 13 or 14 wherein the acid is naphthalene-1,5-disulfonic acid, ethane-1,2-disulfonic acid, dodecylsulfonic acid, naphthalene-2-sulfonic acid, 2-hydroxy-ethanesulfonic acid, or (+)-camphor-10-sulfonic acid.

52. (NEW) The acid addition salt of claim 1 that is the methane sulfonate salt of methyl ALA ester.

53. (NEW) The acid addition salt of claim 1 that is the methane sulfonate salt of hexyl ALA ester.

54. (NEW) The acid addition salt of claim 1 that is the methane sulfonate salt of benzyl ALA ester.

55. (NEW) The acid addition salt of claim 1 that is the toluene sulfonate salt of methyl ALA ester.

56. (NEW) The acid addition salt of claim 1 that is the toluene sulfonate salt of hexyl ALA ester.
57. (NEW) The acid addition salt of claim 1 that is the toluene sulfonate salt of benzyl ALA ester.
58. (NEW) The acid addition salt of claim 1 that is the nitrate salt of benzyl ALA ester.